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US-A- 3 709 222
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D scripti n

Background of the Invention

The invention relates to a dialysis system for purifying the blood by continuous flow of a dialysate and exchange across the peritoneal membrane.

Heretofore, artificial kidney users have relied basically on two processes for purifying the blood. Hemodialysis involves the circulation of blood through a dialysis machine in which an exchange of toxic metabolites takes place across an artificial membrane outside the patient's body. This process requires the assistance of trained personnel and subjects the patient to dangers of mechanical malfunction due to the fact that blood vessels are involved.

Peritoneal dialysis involves the infusion of a sterile dialysate into the peritoneal cavity and after absorbing waste metabolites, the dialysate is discarded. The process is then repeated until the level of metabolites is reduced to a desired level. This method is commonly referred to as the "Batch" method due to the fact that multiple one or two liter bottles or bags of fresh dialysate solution are utilized which require multiple connections to be made to the catheter inserted in the peritoneal cavity during the dialysis process. The multiple connections made during the course of the dialysis has been thought to be a major cause of the high instance of peritonitis.

Continuous ambulatory peritoneal dialysis offers continuous peritoneal dialysis while still allowing the patient some off time. However, the continuous ambulatory peritoneal dialysis must be done in absence of a machine and multiple bottles or bags of dialysis must be infused daily. Thus, multiple infusions per day requires that multiple connections of bags or bottles to the peritoneal catheter be made. The production of bulk sterile dialysis for the peritoneal process has not been known to be practical for large scale application particularly for home dialysis.

United States Patent No. 4,311,587 seeks to avoid some of the above problems with peritoneal dialysis by providing a sub-micron filter on line with the fresh dialysate to prevent peritoneal contamination. The system is perambulatory and the bag of dialysate is worn by the patient. The bag may be pressurized by numerous methods and is connected only to the inflow side of the filter. The outflow port of the filter is connected on th other side of the filter so that no peritoneal contaminating source is connected directly to the peritoneal cavity. The system is still basically a batch type system in that multipl bottles or bags of dialysate must be connected to th filter even though direct connection to th peritoneal catheter is not required.

United States Patent No. 4,338,190 discloses a system and process which attempts to avoid the batch process method utilized heretofore in peritoneal dialysis wherein a closed loop peritoneal circuit is provided having a selective membrane across which toxic metabolites are exchanged. A solution is passed on the other side of the selective membrane for maintaining the original concentration of sugar and salt in the peritoneal fluid as the toxic metabolites pass the separator membrane. A concentrate of sugar and salts is mixed at a desired ratio with water making up the dialysis fluid. The conductivity of the fluid may be automatically monitored to adjust the concentration of the fluid during its recirculation. A double peritoneal catheter provides for the inflow and outflow of the peritoneal fluid. However, the peritoneal fluid is constantly recirculated through the peritoneal cavity and the efficiency becomes reduced slightly because of residual toxins which are put back into the peritoneal cavity. The selective membrane is an expensive disposable item which means that the cost of operating the system is high unless the membrane is recleaned. Pumping the peritoneal fluid through the peritoneal cavity is required making it difficult to assure that the patient stays properly distended during the dialysis process. If the peritoneal membrane is not fully distended, it becomes convoluted around the intestines and pockets are formed where the peritoneal fluid can hide. Incomplete circulation then results with decreased efficiency of dialysis. No control is had over the level of peritoneal fluid in the peritoneal circuit. There is no way of replenishing the peritoneal fluid should the circuit run low on fluid or run dry.

Patent No. 3, 545,438 discloses a batch type peritoneal dialysis method which provides for partially reusing a portion of the dialysis fluid. The spent fluid becomes mixed with fresh dialysate. There is no control or monitoring of the fluid in and out as would allow the dialysate to flow in the peritoneal cavity continuously without dwell time. United States Patent No. 3,707,967, corresponding to German Patent No. 2,149,040, apparently discloses a closed loop dialysis system wherein the dialysis fluid is continuously circulated through the peritoneal membrane. The combination of flow control and monitoring in inflow and outflow lines, and a continuous, cyclic open circuit is not present in the German application. Patent US-A-3,709,222 discloses a periton al dialysis method generally of the batch type. In the '222 patent, th amount of dialysis fluid entering the peritoneal cavity and the pr ssur of the peritoneal cavity are controlled by varying the height of a pressure relief chamber. This can be both inaccurat and unreliable, and

requires that an attendant be present in order to carry out the proc ss. The cycl s involved in the process are rather complicated involving an initial priming cycle which involves the filling of a proportioned chamber, the pressure relief chamber and a return chamber. To begin the process, dialysis fluid is allowed to enter the peritoneal cavity from the pressure relief chamber until the chamber is moved to a lower position which prevents the fluid from flowing. Next, an automatic cycling begins in which the fluid is pumped out of the cavity into the return chamber. Next, an inflow cycle begins in which the fluid is pumped from the return chamber to the proportional chamber which forces fresh dialysis from the proportioning chamber into the pressure relief chamber from where it flows into the patient. Next, there is an equilibrium cycle in which dialysis fluid is drained from the proportioning chamber and fresh dialysis fluid is added. Apparently, during this time, dialysis fluid remains in the cavity. The process then switches back to the outflow cycle in which fluid is pumped from the cavity to the return chamber. French Patent No. 2,371,931 discloses a peritoneal process having a single line used for inflow and outflow. The method includes pumping in a certain amount of dialysate, letting it diffuse for a prescribed dwell time, and removing the dialysate. This is, in essence, an automatic "batch" system.

The present invention relates to improvements in the control of dialysis processes and to the control of the osmolality of the fluid in response to the amount of the fluid removed from the patient. The osmolality is continuously adjusted to ensure the basis of the patient.

Accordingly, an important object of the present invention is to provide a continuous cycle peritoneal dialysis system which avoid the inherent problems and dangers of a batch type peritoneal dialysis system.

Still another important object of the present invention is to provide a peritoneal dialysis system having a high rate of dialysate exchange providing increased dialysis efficiency.

Still another important object of the present invention is to provide a peritoneal dialysis system having a high rate of dialysate exchange and dialysis efficiency in which the osmolality of the fluid is continuously adjusted in response to the amount of fluid removed from the patient.

Still another important object of the present invention is to provide a continuous-flow single-pass peritoneal dialysis system in which th pressur and volum of dialysate in the patient's peritoneal membran may be monitored and set by th patient in a simpl and conveni nt manner without the need of a medical attendant.

Summary of th Inventi n

The above objectives are accomplished according the present invention by a continuous cyclic peritoneal dialysis system in which a continuous flow of sterile dialysis fluid is produced and caused to flow through the peritoneal cavity of the patient in a single-pass open-circuit.

The system comprises a source of a generally continuous supply of sterile dialysis fluid. An inflow line is adapted for connection to said source and to a single-flow peritoneal catheter implanted in the peritoneal cavity of a patient and an outflow line is adapted for connection to said peritoneal catheter. Positive displacement pump means include a fill pump in said inflow line for pumping fluid into said cavity during a fill cycle and a drain pump in said outflow line for pumping said fluid out of said cavity during a drain cycle. Detector means include a fluid column tube connected in fluid communication with said inflow line and outflow line having a high detector for detecting a high level of fluid in said column tube, and a low detector for detecting a low level of fluid in said column tube. Dialysis process controller means control said pump means in response to said detector means starting said fill cycle in response to said low detector, and starting said drain cycle in response to said high detector generally instantaneously with zero fluid dwell timme for fluid in said cavity. Metering means include counters for counting the revolutions per minute of said fill pump and said drain pump for measuring an inflow volume of fluid pumped into said cavity and for measuring an outflow volume of fluid pumped out of said cavity. And a glucose pump has an inlet connected to a source of glucose and an outlet connected to said inflow line, and means for adjusting said glucose pump to vary the amount of glucose delivered into said inflow line in response to said inflow volume and said outflow volume to alter the osmolality of the fluid.

Description of the Drawings

The construction designed to carry out the invention will hereinafter be described, together with other features thereof.

The invention will be more readily understood from a reading of the following specification and by reference to the accompanying drawings forming a part thereof, wherein an example of the invention is shown and wherein:

Figure 1 is a schematic diagram illustrating a continuous flow periton al dialysis syst m and method according to th inv ntion; and

Figur 2 is a sch matic view illustrating a process controller for a continuous cycle peritoneal dialysis system and method according to the

present invention.

Description of a Preferred Embodiment

Referring now in more detail to the drawings, a continuous inflow/outflow peritoneal dialysis process and system is illustrated in Figure 1 which includes a water purification and tempering unit 10 connected to a water source 12. Unit 10 may be any suitable unit for sterilizing and tempering the water, such as a conventional reverse osmosis unit. Unit 10 communicates through ready and enable lines 10a, 10b as shown going up to a process controller, designated generally as A. Unit 10 has no intelligence from the process controller other than ready or not ready. A dialysate proportioning unit 14 receives concentrate dialysate from a source 16 and mixes it with sterilized water from unit 10 to provide a concentrated solution of prescribed proportions of dialysate and water. Unit 14 may be a conventional proportioning pump having a geometry that creates a specific ratio of one fluid to another. One fluid drives the pump, the other is pumped by the pump. The fluids come out at a specific fixed ratio. Unit 14 may also include pressure regulation, temperature sensing, conductivity sensing and by-pass and drain valving. This would allow for the system to function in its three modes of operation. The first mode is the sterilize mode which is the static mode of the machine. It is full of some sterilizing solution, perhaps Clorox. The second mode of operation for the machine would be the rinsing and preparation for dialysis mode. The unit is operated in the second mode until conditions are stable and suitable for patient dialysis. The third mode would be the running mode where actual dialysis process is performed. Unit 14 is controlled by dialysis process controller A which is responding to the sensing that is taking place in unit 14 providing data to the process controller. Process controller A may be any suitable process controller of conventional design well within the capacity of one having average skill in the automatic control art.

The system is started by actuation of a start button 18. Once the process controller has gone through the sterilization and is into the run cycle, the dialysis process controller may begin. A run light 20 on controller A will signal the patient that the machine is ready to operate and may include an additional audio, visual, or both signal to the patient. Next, the patient will connect a tube set 22 from th dialysis processing unit to a single flow catheter 26 disposed in the patient's peritoneal cavity 28 in a conventional manner. Once th patient has connected his tube set, he will press a fill button 30 on the dialysis process controller acknowledging that he has done all of the preparation required and is ready to begin the dialysis procedure. At that point a tim clock 32 on controller A begins to accumulate time as the cycle is now in process. The time clock displays elapsed time at 32a accumulated throughout the entire cycle whether it is terminated by an alarm or by the patient or by a parameter set as a maximum number of cycles. As long as the machine is operating, then elapsed time 32 is accumulating. The process has now begun and the patient is receiving dialysis fluid from a fill pump B. Pump B, preferably of the peristaltic, roller type, pumps fluid from dialysis proportioning unit 14 through line 34 to tube 22 and cavity 28. Pump B is controlled by processor A. For this purpose, pump B is connected by electrical leads 36a, 36b to controller A for delivering speed and volume signals respectively. The patient continues to receive fluid until a comfort level is reached. The patient will manually set a comfort level by pushing a fill-set button 38 when his initial fill has reached a point which he considers to be a comfortable level and feels his cavity slightly distended. Pressing button 38 will indicate to process controller A that is the fill level or volume he wishes to set and to repeat the dialysis process cycles at that particular volume of fluid. The process controller immediately reverses the cycle from fill to drain without any dwell time for the fluid in cavity 28. All the time the machine was filling under fill volume, the amount of fluid pumped into the patient will be metered by counter 40, and accumulated and displayed at display 40a on controller A. The fill volume 40a is an accumulated total as it pertains to one dialysis process for one patient. This corresponds to elapsed time 32a.

The fill cycle stops and the drain cycle instantaneously begins at the point at which the patient pushes fill-set button 38. When the patient presses the fill set button 38, he also sets a slidable high pressure detector 50 on a manometer means D to correspond to this fill volume. A fluid column tube 48 is connected to junction 42 to receive fluid and is oriented vertically in the fashion of a standpipe. A millipore filter 54 vents tube 48 to atmosphere. Column tube 48 includes high fluid and pressure detector 50 and a low level and pressure detector 52 which provide a manometer means D. Detectors 50,52 may be standard photocell detectors, or infrared sensors for detecting the presence or absence of fluid at the high and low levels. For this purpose, the detectors may be mounted on slide brackets 50a, 52a, so that the high/low points may be set to particular points. Th pati nt calibrates th high pressure point by sliding detector 50 to th lev l of fluid seen when th fill set button is pushed. Alternately tube 48 may be slidably mounted. The high and low pr ssur levels will tend to remain constant for a given patient.

Tube 48 is preferably plastic tubing and does not have to be hanging perfectly vertical. This provides a very simple yet sensitive and accurate means of sensing the pressure in the cavity and hence peritoneal volume. As little as 15 centimeters of water, a very slight pressure, may be sensed. After the patient pushes the fill set button and calibrates the high pressure detector 50, operation is automatic. After the fill cycle, controller A, without any dwell, turns on drain pump C, preferably of the peristaltic pump type. The pump begins to drain fluid from cavity 28. Drain pump C is connected via junction 42 to tube 22. Pump C is controlled by controller A and there are leads 44a, 44b connected to the pump. Lead 44a delivers a speed signal to pump C and lead 44b delivers a sensed volume (rpm) signal to controller A. The drain cycle is a function of the fill-pump stopping and the drain pump starting. Fill pump B and drain pump C are positive displacement type pumps which have the ability to both pump and meter fluids. The accumulated fill volume is a function of the pumps pumping in and the drain is a function of pumps pumping out in rpm's. Pump C drains until the pressure in peritoneal cavity 28 no longer supports the column 46 of fluid in column tube 48 attached to junction 42. The fluid height in column tube 48 falls to a prescribed low pressure point detected by lower sensing device 52. Low pressure point 52 may be preset in controller A corresponding to a minimum pressure or it may be calibrated by sliding the detector on the tube. At this point the patient's cavity has drained to a point where the dialysis process has reached diminishing returns. This keeps the cycle time at a minimum. Then the cycle reverses and becomes a fill cycle once again. At this time, the drain volume will be metered by counter 60 and the amount withdrawn from the patient is shown on a controller display 60a as it continues to accumulate. Since this is cycle 1, it will be the exact amount of the initial drain. Cycle run display 62a of cycle counter 62 will increment to 1 showing that the first cycle is completed and another cycle has begun. That cycle will continue until the height of the fluid in the column approaches high pressure sensor 50 and the fluid does not just reach that, it pauses above that and below that. The pumping of pump C is not continuous, it is intermittent pumping action. The pump speed governs the height of the column. As the cavity 28 reaches its fill level, fluid in tube 48 will oscillate rapidly above and below high pressure detector 50 and controller A will slow pump B down. The pump speed has diminished to th point of diminishing returns, the delivery of fluid to the patient is getting ver more slow. When fluid level is generally constant in blocking detector 50, pump B will cut off. Then, the cycle is reversed once again, and a drain cycle is instigated by controller A. The same variable speed operation of pump C occurs during the drain cycle. The reversing cycles continues until the patient terminates it, the maximum time has run out, fill volume has timed out, or until an alarm in the system stops it. At exactly the instant the patient presses stop bottom 64, the pump is pumping dialysis fluid in with the column height pressure level in every instance. The pump is pumping out with the low pressure maintained at low pressure sensor 52 in every instance. It is the pump speed which corresponds to a maintained column height that determines when the cycle trips.

The setting of the fill volume will now be described in more detail. When fill set button 38 is pressed the pump has reached a certain recorded speed. It is filling up column tube 48. The column height is there and the pump, for example, is at approximately 10 r.p.m. The pump starts out running at full r.p.m. which is about 40 r.p.m. The pump continues at full rate until the column reaches high pressure sensor 50. As soon as the liquid hits this level, it is going above it. It has reached this point through acceleration and is going to continue to go above that point unless the speed of the pump is decreased. As the patient accepts fluid and actually creates more resistance to the fluids, it can enter the patient's body less rapidly. The pump has to slow down to maintain the column height. At the point where the patient becomes uncomfortable, he pushes the fill-set button and the machine immediately reverses. There is a corresponding pump speed which corresponds to fill pressure. The patient may press the fill-set button as frequently as he wishes throughout the entire process. For instance at the start one would probably not be as relaxed and the tissue in the abdomen would not have elasticized and perhaps would have a smaller pool areal. After his body becomes accustomed to the process, he may be able to accept more. Therefore, the patient presses the fill button and the system starts the fill until the patient presses the fill-set button. This would then give the patient a different fill volume level. The pressing of the fill-set button creates a memory of the exact conditions of the unit at the time the button is pressed. Fill is a command to fill that will continue until the fill-set button is pressed or until the system reaches an internally programmed maximum values. These values would include physiology safe values. These values, while not always comfortable to the patient, are physically undamaging. In the v nt of an mergency, th patient may hit a drain button 66 and then he may release th connector hoses and be released. The value where th machin automatically goes into the drain mod will presumably be something above the comfort l vel, but not abov a safety

level. This may be preset in the controller. This is not accessible by the pati nt.

Means for regulating the osmolality of the dialysis solution delivered to the patient in response to the amount of the fluid removed from the patient is provided. The regulating means continuously adjusts the osmolality of the solution to ensure that a desired amount of fluid is removed, or in some cases, added. The regulating means includes a glucose pump E, preferably of the peristaltic type, connected to the inflow line upstream of fill pump B and the inlet of pump E is connected to a source of glucose 70. Pump E is controlled by controller A in response to the amount of fluid removed from a patient to adjust the glucose concentrate and osmolality of the dialysate coming from source 16 in order to achieve a desired patient weight loss. It is noted that fill pump B and drain pump C are fixed volume roller pumps which quite accurately serve to meter the amounts of fill and drain fluids. By measuring the number of revolutions per minute of the pump and pumping time, the volume of fill and drain fluid may be accurately metered and determined. The same is true of glucose pump E in regards to the amount of glucose pumped and mixed with the dialysis fluid in order to accurately determine the glucose concentrate and osmolality of the solution. For a given patient, the dry weight of that patient can easily be estimated. By weighing the person before dialysis, the amount of weight loss desired during dialysis can be determined. This determines the amount of fluid removed from the patient during dialysis. Based on the length of time the process is to run, the amount and ratio of glucose needed for the desired weight loss can be determined. Controller A calculates the volume of fill and drain fluid from the volumetric r.p.m. signals on leads 36b and 44b from the respective pumps. By comparing these signals, it can be determined how much fluid is being removed from the patient. If the weight, i.e. fluid, is not being adequately removed, a drive signal is sent to glucose pump E from controller A via lead 72 to speed up the pump, increase the glucose supplied to the dialysis fluid, and increase fluid removal. If too much weight is being removed, the glucose pump is slowed down to reduce the amount and ratio of glucose mixed with the fluid. Adjusting the glucose concentrate and osmolality automatically allows for a standard dialysate solution to be supplied at 16. The concentrate can easily be tailored to the patient by varying the glucose amount via pump E. Providing different pre-prepared dialysates for a variety of pati nts is not necessary as the concentrat may easily be varied in an automatic convenient manner in accordance with the process and system of the inv n-tion. The glucose is automatically varied during th dialysis process to achieve a desired weight loss, or addition if the case may be.

Referring now in more detail to Figure 2, a block diagram of one suitable controller is illustrated. There is a start/stop circuit 80 driven by manual push buttons allows starting, stopping, and continuing of the process without losing the control parameters or data accumulated thus far in the event the patient must adjust for position, comfort or temporary interruptions. A run indicator 80a glows when process is proceeding. A mode 82 circuit determines the fill/drain cycle of operations. Fill and drain manual push buttons 30, 66 may be activated at any time to interrupt the automatic control and force a change to the opposite mode. A fill comparator 84 is connected to a motor drive 86 of pump B and monitors the fill mode and limits the fill speed of pump B to the setting on the maximum fill rate and causes the mode circuit to reverse when the peritoneal pressure during any cycle reaches the predetermined maximum value on the pressure set control. A drain comparator 88 is connected to motor drive 90 of drain motor C and monitors the drain mode to limit the drain speed of pump C to the setting on the maximum drain rate and causes the mode circuit to reverse when the peritoneal pressure during any drain cycle reaches the predetermined minimum value on the preset pressure control. Fill set button 38 is used by the patient during the first fill half-cycle of a treatment to establish the maximum fill volume and store in memory. Patient comfort is the criteria for this setting. Fill/drain indicators 30a, 66a show which mode the system is in at the moment. A fill/drain motor drives 86, 90 send power to their respective motors to provide the pumping action desired. Hi/lo pressure sensors 50,52 monitor the height of the column of dialysate in a tube so placed as to represent the peritoneal pressure. High sensor 50 senses the high pressure level, and low sensor 52 senses the low pressure level. This data is used to control fill/drain rates. Fill/drain motors drive the peristaltic roller mechanisms against the sterile tube-set to pump the dialysate. Fill motor pumps dialysate into the patient's peritoneal cavity. Drain motor pumps the dialysate out of the patient's peritoneal cavity.

A cycle monitor circuit 92 measures the fill and drain volumes of each cycle and compares them to the predetermined values of minimum and maximum volume per half-cycle as set by the minimum volume and maximum volume controls. Should a volum not be in tolerance, a violation signal registers. An abnormal cycl counter 94 counts th violations and if a predetermined number, as set on th abnormal cycle count limit, occur in a row then the process is stopped, drain is initiated, and an alarm circuit 96 is activated. Alarm circuit 96 re-

ceiv s violation signals from either the abnormal cycl count r, th dialysat proportioning unit 14, or the water sterilization unit 10 and triggers an audible alarm and visual alarm until a reset button 98a is pressed. A weight loss counter 100 measures the fill and drain volumes by the pulses from the fill and drain pump sensors 36b, 46b and calculates the instantaneous weight loss volume. A weight loss comparator 102 uses this weight loss value and the elapsed time from elapsed time clock 32 and calculates the weight loss rate which is compared to the predetermined values as set on the weight loss set and treatment duration set controls. If the rate needs to be changed to accomplish the goal, a high or low signal is sent to the adjustable delay time 104. If the treatment has been in progress for the delay time value as set on the delay set control, then an up/down signal is sent to the glucose ratio memory circuit 106 to change the ratio from the predetermined value set on the initial glucose rate. This whole evaluation and adjustment process repeats continuously to accomplish the weight loss goal. A glucose speed control 108 accepts this ratio signal and converts it to a pulse rate which drives the stepper-type glucose motor E through the glucose motor drive 110 to effect a highly accurate glucose mix into the dialysate.

Fill and drain volume counters 40 and 60, respectively, measure and display, in liters, the respective accumulated volumes by counting pulses from the fill and drain sensors 36b, 44b which trigger with each revolution of the peristaltic pumps. Elapsed time clock 32 measures and displays the total time the treatment has been in process in hours and minutes. Cycle counter 62 measures and displays the total number of fill and drain cycles. Reset circuit 98 returns all counters and clocks to zero when the reset push button is pressed for 4 seconds. A power supply 112 supplies electrical current for all elements from the standard 117VAC utility power.

While a preferred embodiment of the invention has been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from scope of the following claims.

Claims

1. A continuous cyclic peritoneal dialysis system comprising:
   a source of a g n rally continuous supply of sterile dialysis fluid;
   an inflow line (34) adapted for connection to said source and to a single-flow peritoneal catheter (26) implanted in the peritoneal cavity (28) of a patient;
   an outflow line (35) adapted for connection to said peritoneal catheter (26);
   positive displacement pump means including a fill pump (B) in said inflow line (34) for pumping fluid into said cavity (28) during a fill cycle and a drain pump (C) in said outflow line (35) for pumping said fluid out of said cavity (28) during a drain cycle;
   detector means including a fluid column tube (48) connected in fluid communication with said inflow line (34) and outflow line (35) having a high detector (50) for detecting a high level of fluid in said column tube (48), and a low level detector (52) for detecting a low level of fluid in said column tube (48);
   dialysis process controller means (A) controlling said pump means in response to said detector means for starting said fill cycle in response to said low detector (52), and for starting said drain cycle in response to said high detector (50) generally instantaneously with zero fluid dwell time for fluid in said cavity (28);
   metering means including counters for counting the revolutions per minute of said fill pump (B) and said drain pump (C) for measuring an inflow volume (36b) of fluid pumped into said cavity (28) and for measuring an outflow volume (44b) of fluid pumped out of said cavity (28);
   a glucose pump (E) having an inlet connected to a source of glucose (70) and an outlet connected to said inflow line (34), and means for adjusting said glucose pump (E) to vary the amount of glucose delivered into said inflow line (34) in response to said inflow volume (36b) and said outflow volume (44b) to alter the osmolality of the fluid.

2. The system of claim 1 wherein at least said high detector (50) and column tube (48) are disposed for relative sliding motion so that said high detector (50) may be set and calibrated manually.

Patentansprüche

1. Kontinuierliches, zyklisches Bauchfell-Dialysesystem, das folgendes umfaßt:
   eine Quelle mit einer im wesentlichen stetigen Zufuhr einer sterilen Dialyseflüssigkeit;
   eine Zuflußleitung (34), di so angepaßt ist, daß si mit d r Quelle und einem einflutigen Bauchf ll-Kath ter (26), der in der Bauchhöhle (28) eines Pati nten implantiert ist, verbunden werden kann;
   eine Ausflußleitung (35), di so angepaßt ist,

daß sie mit dem Bauchfell-Katheter (26) verbunden werden kann;

Verdrängerpumpenanordnung, die eine Füllpumpe (B) in der Zuflußleitung (34) zum Pumpen von Flüssigkeit in die Bauchfellhöhle (28) bei einem Füll-Zyklus und eine Absaugpumpe (C) in der Ausflußleitung (35) zum Abpumpen dieser Flüssigkeit aus der Bauchfellhöhle (28) bei einem Absaug-Zyklus umfassen;

Detektormittel, die eine Flüssigkeitssäulen-Röhre (48) umfassen, die mit der Zuflußleitung (34) und der Ausflußleitung (35) flüssigkeitsmäßig verbunden ist und einen Höchststand-Detektor (50) zur Erfassung eines Flüssigkeitshöchststandes in der Röhre (48) und einen Niedrigstand-Detektor (52) zur Erfassung eines Flüssigkeitsniedrigstandes in der Röhre (48) umfaßt;

Steuermittel (A) für den Dialyseprozess zur im wesentlichen verzögerungsfreien Steuerung der Pumpen entsprechend der Detektormittel, zum Starten des Füll-Zyklus, entsprechend dem Niedrigstand-Detektor (52), und zum Starten des Absaug-Zyklus, entsprechend dem Höchststand-Detektor (50), ohne Verweilzeit der Flüssigkeit in der Bauchfellhöhle (28);

Meßmittel in Form von Zähleinrichtungen zum Zählen der Umdrehungen pro Minute der Füllpumpe (B) und der Absaugpumpe (C), zum Messen eines Füllvolumens (36b) der in die Bauchfellhöhle (28) gepumpten Flüssigkeit und zum Messen eines Ausflußvolumens (44b) der aus der Bauchfellhöhle (28) gepumpten Flüssigkeit;

eine Glukosepumpe (E), die eine mit einer Glukose-Quelle (70) verbundene Einströmungsöffnung und eine mit der Zuflußleitung (34) verbundene Ausflußöffnung besitzt, und Mittel zum Einstellen der Glukosepumpe (E) besitzt, um die in die Zuflußleitung (34) eingebrachte Glukosemenge entsprechend dem Füllvolumen (36b) und dem Ausflußvolumen (44b) zu variieren und die Osmolarität der Flüssigkeit zu ändern.

2. System nach Anspruch 1, worin mindestens der Höchststand-Detektor (50) und die Röhre (48) für eine relative Gleitbewegung angeordnet sind, so daß der Höchststand-Detektor (50) manuell eingestellt und kalibriert werden kann.

Revendications

1. Système d dialyse péritonéal cycliqu continue comprenant :

   une source d'approvisionnement généralement continue en fluide de dialyse stéril ;

   un tube d'amené (34) conçu pour être relié à ladite source et un cathéter péritonéal à écoulement uniqu (26) implanté dans la cavité péritonéale (28) d'un patient ;

   un tube de sortie (35) conçu pour être relié audit cathéter péritonéal (26) ;

   des moyens de pompage volumétrique comprenant une pompe de remplissage (B) dans ledit tube d'amenée (34) pour pomper du fluide dans ladite cavité (28) au cours d'un cycle de remplissage et une pompe de vidange (C) dans ledit tube de sortie (35) pour pomper ledit fluide hors de ladite cavité (28) au cours d'un cycle de vidange ;

   des moyens détecteurs comprenant un tube à colonne fluide (48) relié en communication fluide audit tube d'amenée (34) et un tube de sortie (35) ayant un détecteur de niveau élevé (50) pour détecter un niveau élevé de fluide dans ledit tube à colonne (48), et un détecteur de niveau bas (52) pour détecter un niveau bas de fluide dans ledit tube à colonne (48) ;

   des moyens de commande de l'opération de dialyse (A) commandant lesdits moyens de pompage en réponse auxdits moyens détecteurs pour faire démarrer ledit cycle de remplissage en réponse audit détecteur de niveau bas (52), et pour faire démarrer ledit cycle de vidange en réponse audit détecteur de niveau élevé (50), d'une manière généralement instantanée, avec un temps de séjour zéro du fluide dans ladite cavité (28) ;

   des moyens de dosage comprenant des compteurs pour compter les tours par minute de ladite pompe de remplissage (B) et de ladite pompe de vidange (C) pour mesurer un volume d'entrée (36b) de fluide pompé dans ladite cavité (28) et pour mesurer un volume de sortie (44b) de fluide pompé hors de ladite cavité (28) ;

   une pompe à glucose (E) ayant une entrée reliée à une source de glucose (70) et une sortie reliée audit tube d'amenée (34) et des moyens pour ajuster ladite pompe à glucose (E) pour faire varier la quantité de glucose délivrée dans ledit tube d'amenée (34) en réponse audit volume d'amenée (36b) et audit volume de sortie (44b) pour modifier l'osmolalité du fluide.

2. Système selon la revendication 1, dans lequel au moins ledit détecteur de niveau élevé (50) et ledit tube à colonn (48) sont disposés n vu d'un mouv ment d glissement relatif d tell sorte que ledit détecteur d niveau élevé (50) puisse êtr réglé t étalonné manuellem nt.

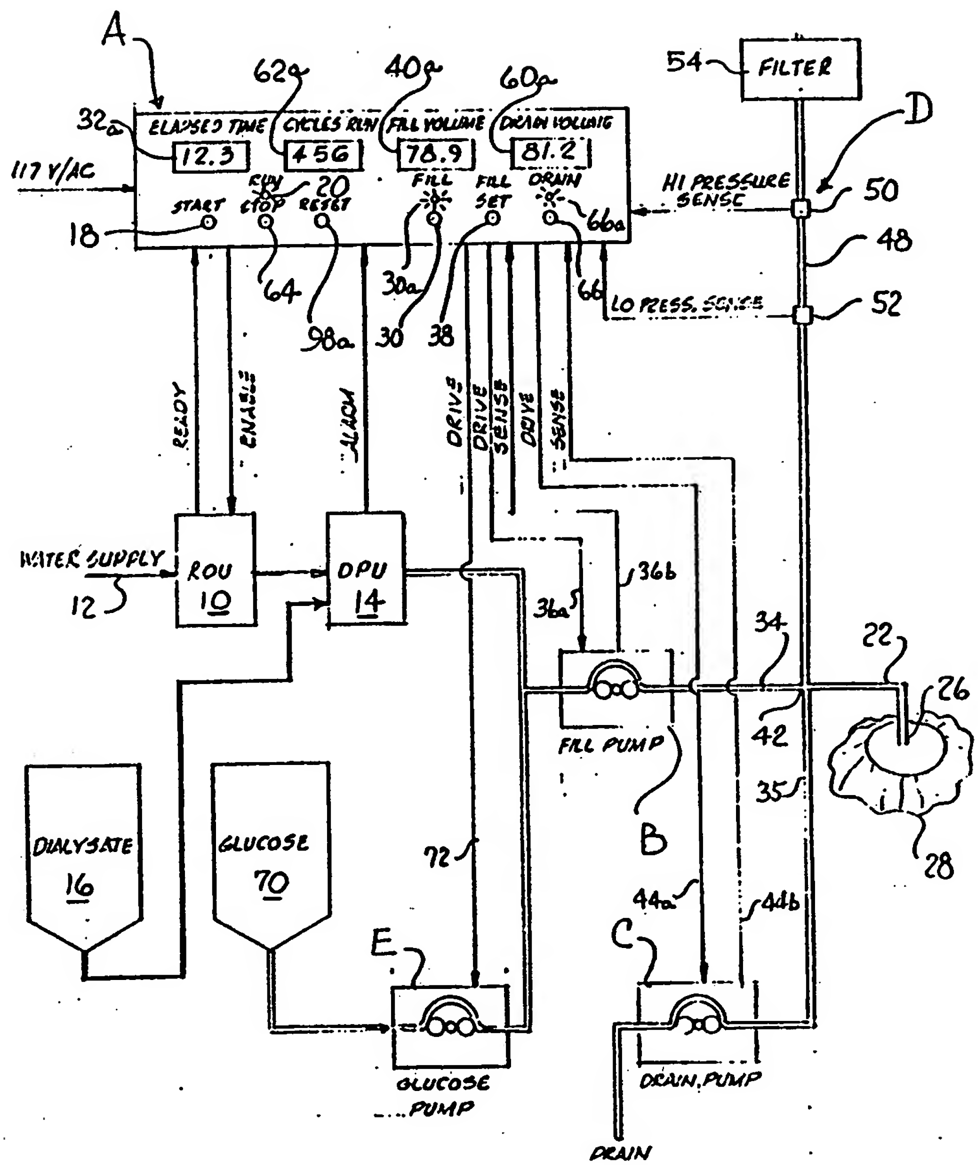
A
32a
62a
40a
60a
54
FILTER
D
ELAPSED TIME
CYCLES RUN
FILL VOLUME
DRAIN VOLUME
12.3
456
78.9
81.2
117 V/AC
START
RUN STOP
20
RESET
FILL
FILL SET
DRAIN
66a
HI PRESSURE SENSE
50
48
18
64
98a
30a
30
38
66
LO PRESS. SENSE
52
READY
ENABLE
ALARM
DRIVE
DRIVE
SENSE
DRIVE
SENSE
WATER SUPPLY
12
ROU
10
DPU
14
36a
36b
34
22
26
FILL PUMP
42
35
B
28
DIALYSATE
16
GLUCOSE
70
72
44a
44b
E
C
GLUCOSE PUMP
DRAIN PUMP
DRAIN

Fig. 1

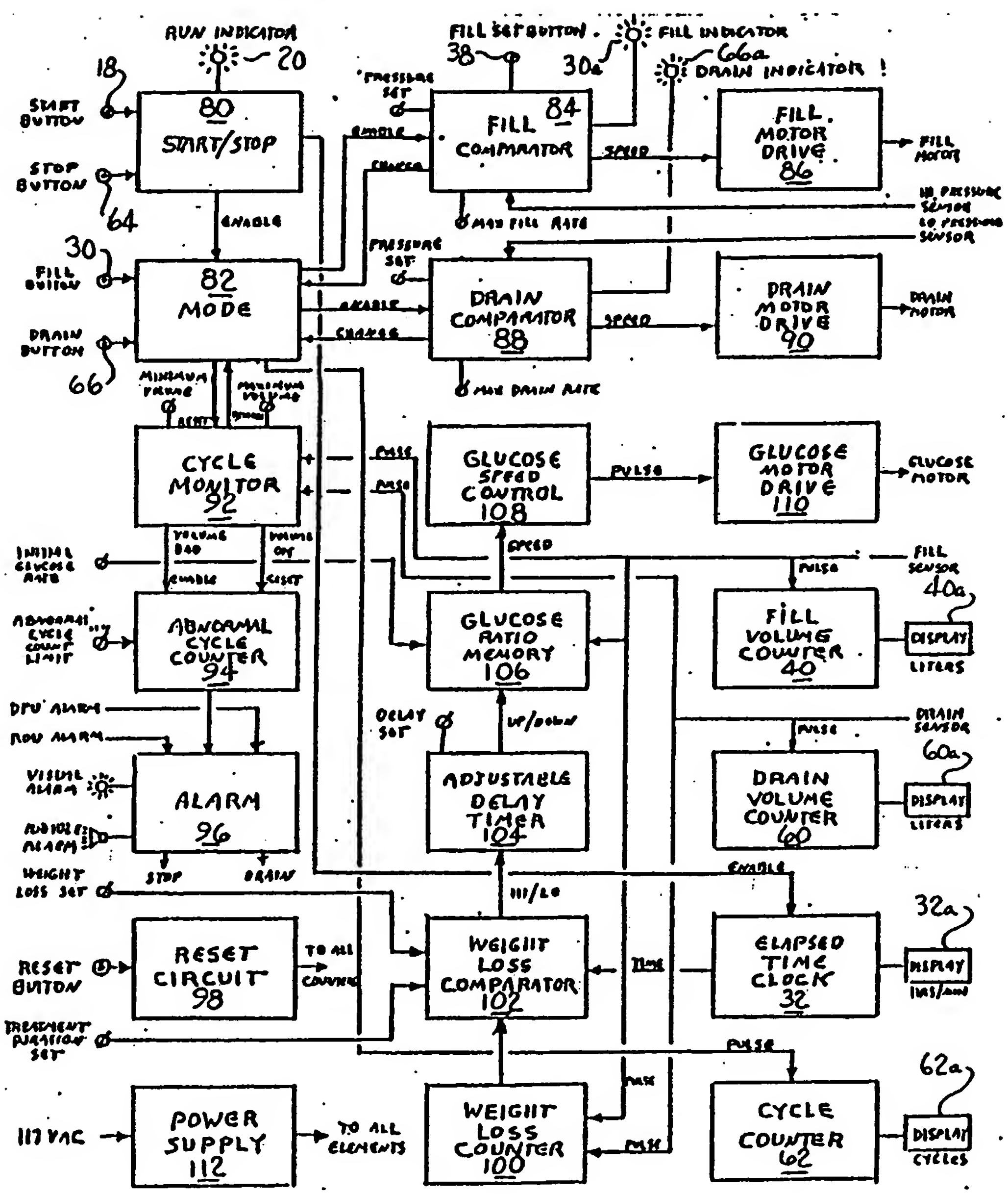
RUN INDICATOR
20
18
START BUTTON
STOP BUTTON
64
80
START/STOP
ENABLE
30
FILL BUTTON
DRAIN BUTTON
66
82
MODE
FILL SET BUTTON
38
30a
FILL INDICATOR
66a
DRAIN INDICATOR
PRESSURE SET
ENABLE
CHANGE
84
FILL COMPARATOR
SPEED
MAX FILL RATE
FILL MOTOR DRIVE
86
FILL MOTOR
HI PRESSURE SENSOR
LO PRESSURE SENSOR
PRESSURE SET
DRAIN COMPARATOR
88
SPEED
MAX DRAIN RATE
DRAIN MOTOR DRIVE
90
DRAIN MOTOR
MINIMUM VOLUME
MAXIMUM VOLUME
CYCLE MONITOR
92
PULSE
GLUCOSE SPEED CONTROL
108
PULSE
GLUCOSE MOTOR DRIVE
110
GLUCOSE MOTOR
INITIAL GLUCOSE RATE
VOLUME BAD
ENABLE
RESET
SPEED
FILL SENSOR
PULSE
40a
ABNORMAL CYCLE COUNT LIMIT
ABNORMAL CYCLE COUNTER
94
GLUCOSE RATIO MEMORY
106
FILL VOLUME COUNTER
40
DISPLAY
LITERS
DPU ALARM
ROU ALARM
DELAY SET
UP/DOWN
DRAIN SENSOR
PULSE
60a
VISUAL ALARM
AUDIBLE ALARM
ALARM
96
ADJUSTABLE DELAY TIMER
104
DRAIN VOLUME COUNTER
60
DISPLAY
LITERS
WEIGHT LOSS SET
STOP
DRAIN
HI/LO
ENABLE
32a
RESET BUTTON
RESET CIRCUIT
98
TO ALL COUNTERS
WEIGHT LOSS COMPARATOR
102
TIME
ELAPSED TIME CLOCK
32
DISPLAY
TREATMENT DURATION SET
PULSE
62a
117 VAC
POWER SUPPLY
112
TO ALL ELEMENTS
PULSE
WEIGHT LOSS COUNTER
100
PULSE
CYCLE COUNTER
62
DISPLAY
CYCLES

Fig. 2